DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1500d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

July 9, 2001

James Yoshioka
Chief Executive Officer
Henry Mayo Newhall Memorial Hospital
Ambulatory Care Imaging Center
25751 West McBean Parkway
Valencia, CA 91355

W/L Number: 60-01
Inspection ID: 1932500009
CFN: 2030206
FEI: 1000519325

Dear Mr. Yoshioka:

We are writing to you because on May 30, 2001, your facility was inspected by a representative of the State of California acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- Level 1: Phantom quality control (QC) records were missing for at least 4 weeks for unit #4 (a [redacted] machine, model [redacted] serial number [redacted] which is located in the mammography room.

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed

Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office, in writing, within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations; and
- please provide sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445
Phone: (949) 798-7600

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, PO Box 6057, Columbia, MD 21045-6057 (telephone number 1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,

Alonza E. Cruse
District Director

cc:

State of California
Department of Health Services
Radiological Health Unit
550 South Vermont Avenue, Suite 601
Los Angeles, CA 90020

Ms. Priscilla F. Butler
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